

19 May 2006

Program Manager USDA/AMS/TMP/NOP 1400 Independence Avenue SW Room 4008-So., Ag Stop 0268 Washington, DC 20250

Dear Sir/Madam,

To assure that certain colors from natural sources remain on the NOP National List of non-organically produced ingredients we offer you the attached petitions for six different color categories.

Colors from Fruit Juices as set forth in 21 CFR 73.250
Colors from Vegetable Juices as set forth by 21 CFR 73.260
Beta-Carotene from natural sources as set forth by 21 CFR 73.95
Colors from Annatto as set forth by 21 CFR 73.30
Colors from Turmeric as set forth by 21 CFR 73.600
Colors from Paprika as set forth by 21 CFR 73.340

We understand that these petitions for colors are now absolutely essential for the NOSB to approve them so colors remain on the National List after Sunset on October 21, 2007. We have used the petition application form that is available on the NOP website. We have also included applicable flow charts for each of these six color categories. We look forward to working with you to assure that these colors from natural sources remain on the NOP National List well beyond October of 2007. If you have any questions or if you require any additional information, please do not hesitate to contact us.

Yours truly

John T. Martin

Director, Scientific & Regulatory Affairs

WILD Flavors, Inc. P: 859-342-3798

F: 859-342-3738 Email: jtmartin@wildlflavors

WILD Flavors, Inc.

#### EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance: Turmeric 21 CFR 73.600 N/A Ouestion Yes No Documentation TAP: petition: regulatory agend 1. Are there adverse effects on  $\overline{\mathbf{x}}$ environment from manufacture. use, or disposal? [§205.600 b.2] 2. Is there environmental X contamination during manufacture, use, misuse, or disposal? [§6518 m.3] 3. Is the substance harmful to the X environment? [§6517c(1)(A)(i);6517(c)(2)(A)i] 4. Does the substance contain List  $\overline{\mathbf{x}}$ 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2] 5. Is there potential for X detrimental chemical interaction with other materials used? [§6518 m.1] 6. Are there adverse biological X and chemical interactions in agroecosystem? [§6518 m.5] 7. Are there detrimental  $\overline{\mathbf{x}}$ physiological effects on soil organisms, crops, or livestock? [§6518 m.5] 8. Is there a toxic or other adverse X action of the material or its breakdown products? [§6518 m.2] 9. Is there undesirable persistence X or concentration of the material or breakdown products in environment?[§6518 m.2] 10. Is there any harmful effect on X human health? [ $\S6517 c(1)(A)(i)$ ; 6517 c(2)(A)i; §6518 m.4] 11. Is there an adverse effect on X human health as defined by applicable Federal regulations? [205.600 b.3] 12. Is the substance GRAS when X 21 CFR 73.600 used according to FDA's good manufacturing practices? [§205.600 b.5] 13. Does the substance contain  $\overline{\mathbf{x}}$ residues of heavy metals or other

contaminants in excess of FDA tolerances? [§205.600 b.5]

<sup>&</sup>lt;sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance: <u>Turmeric 21 CFR 73.600</u>

Control of the Contro	28.50	- 200	435	
Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or	100000000000000000000000000000000000000	X	*100758794658 980	A LATA Printers, regulatory agency, other)
manufactured by a chemical				
process? [6502 (21)]				·
2. Is the substance formulated or		X		
manufactured by a process that				
chemically changes a substance	İ			
extracted from naturally				
occurring plant, animal, or				
mineral, sources? [6502 (21)]				
3. Is the substance created by	X			
naturally occurring biological				
processes? [6502 (21)]				
4. Is there a natural source of the	X			Turmeric is of natural origin
substance? [§205.600 b.1]			,	
5. Is there an organic substitute?		X		
[§205.600 b.1]				
6. Is the substance essential for			X	
handling of organically				
produced agricultural products?	}			
[§205.600 b.6]			ļ	
7. Is there a wholly natural			X	
substitute product?				
[§6517 c (1)(A)(ii)]				
8. Is the substance used in			X	
handling, not synthetic, but not				
organically produced?				
[§6517 c (1)(B)(iii)]	<b> </b>	37		
9. Is there any alternative		X		
substances? [§6518 m.6]	<b> </b>	77	-	
10. Is there another practice that would make the substance		X		
unnecessary? [§6518 m.6]	<u></u>			

 $<sup>^{1}</sup>$ If the substance under review is for crops or livestock production, all of the questions from 205.600 (b)are N/A—not applicable.

### Category 3. Is the substance compatible with organic production practices?

Substance <u>Turmeric</u> 21 CFR 73.600

	Name and Address of the Owner, where the Owner, which is the Owner, where the Owner, which is the Owner, where the Owner, which is the Owner, whic	Marketon V	Mineral	
of pertion	Yes		rky (c	Documentation (TAP: petrion, regulatory agency, bither)
1. Is the substance compatible		-	X	TO PROCESS TO THE PARTY OF THE
with organic handling?				
[§205.600 b.2]	Ì			
2. Is the substance consistent			X	
with organic farming and				
handling? [§6517 c (1)(A)(iii);		ł		
6517 c (2)(A)(ii)]				
3. Is the substance compatible			X	
with a system of sustainable				
agriculture? [§6518 m.7]				
4. Is the nutritional quality of the			X	
food maintained with the				
substance? [§205.600 b.3]				·
5. Is the primary use as a		X		
preservative? [§205.600 b.4]				
6. Is the primary use to recreate	X			And the state of t
or improve flavors, colors,				
textures, or nutritive values lost				
in processing (except when				
required by law, e.g., vitamin D				
in milk)? [205.600 b.4]				
7. Is the substance used in		X		
production, and does it contain				
an active synthetic ingredient in	1			
the following categories:				
a. copper and sulfur compounds;				
b. toxins derived from bacteria;		X		
c. pheromones, soaps,		X		
horticultural oils, fish emulsions,				
treated seed, vitamins and				
minerals?				
d. livestock parasiticides and		X		
medicines?				
e. production aids including		X	<b>-</b>	
netting, tree wraps and seals,		Λ		
insect traps, sticky barriers, row				
covers, and equipment cleaners?				
co vois, and equipment eleaners:				

<sup>&</sup>lt;sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Item A – This petition involves the continued inclusion of exempt colors from turmeric described in 21 CFR 73.600 as a non-agricultural (non-organic) substance allowed in or on processed products labeled as "organic" or "made with organic".

#### Item B

- 1,) Turmeric Color
- 2.) WILD Flavors, Inc. 1261 Pacific Avenue Erlanger, KY 41018 859-342-3600
- 3.) To add color to food/beverages using exempt colorants from natural sources of turmeric
- 4.) Not intended for use on crops or livestock. Adding color is the mode of action.
- 5.) See attached flow chart
- 6.) Not applicable WILD Flavors is not currently a certified manufacturer/handler
- 7.) Refer to 21 CFR 73.600
- 8.) CAS number not applicable
- 9.) Refer to evaluation criteria
- 10.) Not applicable MSDS available upon request. Fruit juices are not considered to be hazardous.
- 11.) All categories of turmeric colors are approved for use in accordance with 21 CFR 73.600 and are GRAS.
- 12.) Non-synthetic colors should remain on the National List as described in 7 CFR 205.605

# NOSB RECOMMENDED DECISION Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting:	Substance:	:			A 1884 A 1844			
A. Evaluation Criteria (Documentation attached; committee recommendation attached)								
		Criteria	Satisfie	ed?				
1. Impact on huma	ans and environm	ent		Yes	No	(see B	below)	
<ol><li>Availability crite</li></ol>	eria			Yes	No	(see B	below)	
<ol><li>Compatibility &amp;</li></ol>	consistency			Yes	No	(see B	below)	
C. Proposed An			notation:					
B. Substance fails criteria		C. Proposed Annotation:						
Criteria category:		Basis for annota	tion:					
Comments:		To meet criteria	above:	_ Crite	ria:			
		Other regulatory	criteria:	_ Cita	tion:			
D. Final Board Action & \	ote: Motion by	•	Sec	ond:				
<u>Vote</u> :	Agricultural	Nonagricul	tural	Crops				
Yes:	Synthetic	Not synthe		Livesto	<del></del>			
	Allowed <sup>1</sup>	Prohibited <sup>2</sup>		Handlir	ng	$\top$		
No:	No restriction	Deferred4		Rejecte		$\top$	•	
Abstain:		<del></del>						
	1—substance vo	ted to be added a	s "allowed" o	n Nationa	al List			
Annotation:								
	0		15-14		4	11.1-1		
Describe why a prohibited		be added to "proh	ibited" parag	rapn of N	iational	LIST		
	3—substance wa	as rejected by vote	for amendin	g Nation	al List			
Describe why material wa	s rejected:							
	4		h - d - f - m - d					
Describe why deferred; if	4-substance was any follow-up is n	recommended to eeded. If follow-u	pe aererrea p needed, wt	no condu	cts folio	ow-		
up								
								_
E. Approved by NOSB C	hair to transmit to	NOP:						
Dave Carter, NOSB Chair						_		
F. NOP Action: Include in FR to amend National List:								
Return to NOSB Reason:								
Richard H. Mathews, Program Manager								
Richard H. Mathews, Program Manager Date								

## NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

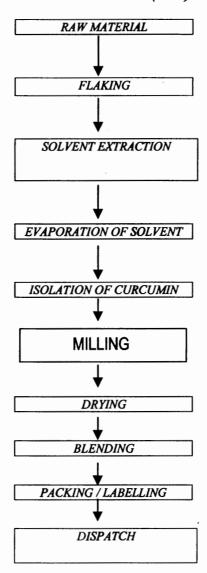
For NOSB Meeting:			Substance:			
Committee: Crops	Livestock	Handling				
A. Evaluation Criteria (Do	ocumentation atta	ched; committee r	ecommendation at	tached)		
•			Crite	ria Satisf	ied?	
Impact on humans and environment			Yes	No	(see B below)	
<ol><li>Availability crite</li></ol>	ria		Yes	No	(see B below)	
6. Compatibility &	consistency		Yes	No	(see B below)	
		C. Proposed An	notation:			
B. Substance fails criteria	1?					
Criteria category:		Basis for annota	tion:			
Comments:		To meet criteria	above: C	riteria:		
·						
		Other regulatory	criteria:	itation:_		
D. Recommended Comm	nittee Action & Vo	te: Motion by:				
		, -				
		Seconded			<del></del>	
<u>Vote</u> :	Agricultural	Nonagricul	tural Cro	ps		
Yes:	Synthetic	Not synthe	tic Live	stock		
No:	Allowed <sup>1</sup>	Prohibited <sup>2</sup>	Har	dling		
	No restriction	Deferred4	Rej	ected <sup>3</sup>		
Abstain:						
Annotation:		oted to be added as	s "allowed" on Nat	onal List		
2—substance to be added to "prohibited" paragraph of National List						
Describe why a prohibited substance:						
Describe why material wa	3—substance was rejected:	as rejected by vote	for amending Nat	ional List		
4-substance was recommended to be deferred  Describe why deferred; if follow-up is needed. If follow-up needed, who will follow up						

E. Approved by Committee Ch	nair to transmit to NOSB:		
Committee Chair	Ō	late	

Turne Prinder

Flow Chart

Oleoresin Turmeric (T-14)



Flow Chart
Oleoresin Turmeric (T-5)

